

REMARKS

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested. Claims 3, 15-17, and 19-21 are canceled without prejudice and claim 1 is amended solely for purposes of clarity. With the above amendment, claims 1-2, 4, and 6-8 are pending. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

The Action rejects claims 1-4 and 6-8 under 35 U.S.C. § 112, first paragraph, as allegedly being non-enabled with regard to the scope. More particularly, the Action maintains that the claims of the instant application are not enabled for the currently encompassed scope because a myriad of inoperative antigenic components of non-infectious *Coxiella burnetii*, some with the demonstrated non-therapeutic or non-prophylactic effect against IDDM, are currently encompassed in the scope of the method claims. Applicants note that the rejection of claims 15-16 and 19-21 under this section has been withdrawn.

Applicants respectfully traverse this basis for rejection of claims 1-4 and 6-8 and submit that claim 1 recites a functional limitation which would necessarily exclude inoperative embodiments. In particular, claim 1 recites "effective amount". Consequently, any inoperative embodiments (*e.g.* antigenic components which would not be effective in preventing or treating autoimmune disease) could not be administered in an effective amount as recited in the claim. Furthermore, Applicants submit that the mere presence of some inoperative embodiments within the scope of a claim does not render a claim nonenabled. The standard is whether one of skill in the art could determine which embodiments would be inoperative without undue experimentation. (see MPEP 2164.08(b)). Applicants submit that the skilled artisan would readily appreciate in light of the instant specification how to determine the antigenic components of non-infectious *Coxiella burnetii* lacking therapeutic and/or prophylactic effect against IDDM. Furthermore, the skilled artisan would readily recognize the routine nature of determining the

inoperative components of non-infectious *Coxiella burnetii*, particularly given the teachings in the instant specification (see for example, Examples 1-5 where non-infectious *C. brunetii* is used to ameliorate IDDM which spontaneously develops in the NOD mouse model system). Moreover, the Cowden Declaration confirms this notion by demonstrating using common procedures known to those of ordinary skill, that a delipidated extract of *C. Burnetii* containing one or more components of *C. burnetii* (i.e., an extracted fraction containing active components that are in-sum less than the whole) can be distinguished from *C. burnetii* components contained in, comparatively speaking, an inactive fraction. In a similar manner, active components of *C. burnetii* may be distinguished from inactive components by way of DMSO extraction. Applicants submit, therefore, that the demonstrated use of active components in the widely accepted IDDM model system, the NOD mouse, using equally well accepted procedures to prepare fractions containing such active components, clearly sets forth and teaches how to practice the instant invention, without undue experimentation, to the full scope as currently claimed, as would be appreciated by those of ordinary skill in the art at the time the instant application was filed. Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph, Indefiniteness

Claims 1-4 and 6-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Action alleges that claim 1 is confusing in the recitation of "treatment.....autoimmune-preventing effective amount". The Action further alleges that claim 1 as amended and claim 3 appear to be redundant or duplicative in scope. Finally, the Action notes that claims 1 and 15 are incorrect in the recitation "a prophylaxis or treatment".

Applicants submit that the above rejection has been obviated by the present amendment of claim 1 and cancellation of claims 3, 15, and 17. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 15-17 and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zhang et al or Gajdosova et al. or Vodkin et al. or Williams et al. The Action alleges that the claimed therapeutic compositions for use in a prophylaxis or treatment of an insulin-dependent diabetes mellitus autoimmune disease in a mammal, said composition comprising non-infectious *Coxiella burnetii* or one or more antigenic components therefrom and one or more pharmaceutically acceptable carriers and/or diluents are taught in the above-cited references.

In order to expedite prosecution of the application and without acquiescing to the Action's rejection, Applicants have cancelled claims 15-17 and 19-21, without prejudice to prosecution of any subject matter removed by this amendment in a related divisional, continuation or continuation-in-part application. Accordingly, Applicants submit that the rejection has been obviated and may be properly withdrawn.

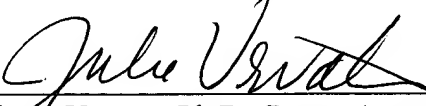
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

William Butler Cowden et al.

SEED Intellectual Property Law Group PLLC



Julie A. Urvater, Ph.D., Patent Agent
Registration No. 50,461

WTC:jto

Enclosure:

Postcard

701 Fifth Avenue, Suite 6300

Application No. 09/142,59
Reply to Office Action dated January 2, 2003

Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

D:\NrPortbl\iManage\JOHNO\348282_1.DOC